



## Reproductive Health Technologies Project

Department of Health and Human Services  
Food and Drug Administration  
[Docket No. 00n-1256]  
Center for Drug Evaluation and Research  
"Over-the-Counter Drug Products"  
June 28-29, 2000

statement of  
Kirsten Moore, Project Director

My name is Kirsten Moore and I direct the Reproductive Health Technologies Project. This advocacy NGO works to influence the commercial and political environment in the U.S. Our goal is to give women and men more options for preventing unwanted pregnancy and disease and to ensure better access to existing options. The Project does not receive any funding from pharmaceutical companies.

For eight years, the Project has considered emergency contraception one of the highest priorities for women's health in America. If taken within 72 hours of unprotected intercourse, emergency contraceptive pills (ECPs) can significantly reduce the risk of an unintended pregnancy. Recent clinical data from the World Health Organization also shows that the sooner women take ECPs the more effective they are. ECPs should not be confused with the so-called "abortion pill." If a pregnant woman uses ECPs, these pills will have no effect on her fetus.

The Project strongly supports over the counter status for these safe, effective and simple pills. Over the counter status will mean that American women can take the pills *sooner* after unprotected sex, therefore preventing more unwanted pregnancies. In evaluating whether to move ECPs OTC, the Food and Drug Administration should consider the following with regard to safety and efficacy.

- 1) Like other OTC products now on the market, ECPs are indicated for a self-diagnosable condition – unprotected sex within the past 72 hours. A clinician is not necessary to diagnose this condition nor prescribe treatment.
- 2) The current clinical consensus is that there are no contraindications to use of ECPs other than an already established pregnancy (ECPs are not effective in that instance). Making ECPs available OTC would not enhance or increase any risk of complications.
- 3) ECPs cause fewer and less severe side effects than many other OTC products. For example, pain-relieving products such as aspirin and Tylenol have been shown to cause serious complications such as gastrointestinal bleeds and liver failure. ECPs should not be held to a higher standard than such widely used products.
- 4) ECPs are already offered de facto OTC by a number of providers. For example, a recent study of the national emergency contraception Hotline revealed that many providers do not require a physical exam and some, including several Planned Parenthood clinics, will phone in a prescription to a nearby pharmacy.

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- 5) Contrary to the belief of some, studies show that women use emergency contraception as responsibly as they use any other drug. A recent study in Scotland showed that women were more likely to use ECPs once but not repeatedly; had a lower pregnancy rate; and were not less likely to use an ongoing method when ECPs were prescribed in advance compared to when ECPs were available only after the fact from a clinician.

Although not related to the safety and effectiveness of ECPs themselves, it is true that some women who have had unprotected intercourse have also been exposed to sexually transmitted infections. The manufacturers of both Plan B and Preven have incorporated a voluntary notice on their packaging reminding women to seek STD screening if they believe they are at risk. Any OTC product should carry similar labeling.

The most compelling reason for moving ECPs over-the-counter is to expand access. Our experience shows that many women have difficulty accessing ECPs. The Project operates the national toll-free Hotline – 888-Not-2-Late. The Hotline provides information about emergency contraception and also gives callers the names and telephone numbers of five providers nearest them who prescribe or dispense emergency contraception. (Although it should be noted that if you're calling from states like Arkansas, Mississippi, or South Dakota, fewer than five providers are listed for the entire state!) Callers can also leave messages for us on the Hotline. Nearly all of these are simple thank you's, but let me share a few recent typical comments relevant to today's hearing:

- ▶ "I had no luck in reaching a doctor who could give me a prescription for emergency contraception. [...] Please call me right away because I need this resource." *Young woman in 215 area code, May 26, 2000*
- ▶ "I'm calling from Los Angeles, California. I've had a completely fruitless attempt to try and get Plan B. [...] Of course I need it today ... *Young woman in 323 area code, June 6, 2000.*

Unfortunately, these women are not alone. Even under the best of circumstances – women who know they want ECPs and who place calls during regular business hours to a group of self-selected providers – are often not able to find emergency contraception within the necessary 72-hour window. Imagine the frustration or even panic of a woman trying to find emergency contraception on a weeknight or on a Saturday during a long weekend. These women aren't simply inconvenienced. Despite their best efforts, they are facing the very real prospect of an unwanted pregnancy. Or imagine the woman who tracks down a prescription but then is told by a pharmacist that she won't fill it because they have a religious objection to ECPs! Moving ECPs OTC is the best mechanism to ensure that responsible behavior is not held hostage to someone else's personal point of view.

Finally, while the women's health advocacy community is strongly united in its assessment of the safety, efficacy, and net public health benefits of OTC emergency contraceptive pills, we do have one concern: insurance reimbursement. Women on a fixed or low-income may not be able to afford an OTC product if their health insurance does not reimburse them for it the way it reimburses for prescription medications. For this reason, we strongly encourage the FDA to consider maintaining dual status for ECPs and allow the same product or similar products to be available OTC and Rx.

On behalf of the board of the Reproductive Health Technologies Project, thank you for this important opportunity to comment on the FDA's OTC Drug Review Process.